

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

SYNGENTA CROP PROTECTION, INC.)	
)	
Plaintiff,)	
)	
v.)	1:02CV334
)	
UNITED STATES ENVIRONMENTAL)	
PROTECTION AGENCY,)	
)	
STEPHEN L. JOHNSON, Administrator)	
U.S. Environmental Protection Agency,)	
)	
MAKHTESHIM-AGAN OF NORTH)	
AMERICA, INC.,)	
)	
SIPCAM AGRO USA, INC.,)	
)	
DREXEL CHEMICAL COMPANY, and)	
)	
ALBAUGH, INC.)	
)	
Defendants.)	
)	

MEMORANDUM OPINION

TILLEY, Chief Judge

This suit arises from a dispute between Plaintiff Syngenta Crop Protection, Inc. ("Syngenta") and Defendants United States Environmental Protection Agency and its Administrator, Stephen L. Johnson¹ (collectively "EPA"), Makhteshim-Agan of North America, Inc. ("MANA"), Sipcam Agro USA, Inc. ("Sipcam"), Drexel

¹ This suit was initially filed against Christine Todd Whitman, the previous Administrator of the EPA, in her official capacity. The current Administrator, Stephen L. Johnson, has been substituted as the proper defendant in this case.

Chemical Company ("Drexel"), and Albaugh, Inc. ("Albaugh"), regarding registrations of the pesticide metolachlor.² This case currently has numerous discovery motions outstanding.³ Although these pretrial matters are best addressed by the Magistrate Judge, several of them depend on a determination of whether Syngenta's claim regarding the EPA's substantial similarity determination is reviewable by this Court.⁴ Thus, to aid in the resolution of the outstanding

² Defendants MANA, Sipcam, Drexel, and Albaugh will be referred to collectively as "Private Defendants."

³ The following pretrial motions are currently awaiting decision: (1) Syngenta's Motion for Supplementation of the Administrative Record and for Limited Discovery on Count IV and VII [Doc. #77]; (2) Syngenta's Motion to Attach Exhibit to Plaintiff's Opposition to Defendant EPA's Motion to Dismiss [Doc. #91]; (3) MANA's Motion to Supplement the Administrative Record [Doc. #167]; (4) Drexel's Motion to Exclude Documentation from Administrative Record [Doc. #171]; (5) Syngenta's Motion for Order Requiring Production of Document in the Administrative Record as to which EPA has made a Meritless Claim of Privilege [Doc. #173]; (6) Syngenta's Motion to Amend Protective Order Governing Confidentiality [Doc. #175]; (7) Syngenta's Motion to Supplement the Administrative Record [Doc. #177]; (8) Sipcam's Motion to Exclude Certain Confidential Information from the Administrative Record [Doc. #179]; (9) Defendants Drexel, Sipcam, MANA, and Albaugh's Motion for Protective Order Governing Confidentiality [Doc. #181]; (10) Defendants Sipcam, Drexel, MANA and Albaugh's Motion to Strike Declaration of Richard Fuller [Doc. #188]; (11) EPA's Motion to Strike Declaration of Richard Fuller [Doc. #194]; and (12) Syngenta's Motion for Status Conference to address case management issues [Doc. #219].

⁴ For example the Private Defendants claim information regarding safeners – inert ingredients incorporated into end use pesticides – are highly confidential and trade secret in nature. However Syngenta now requests this information be included in the Administrative Record because it is relevant to whether the EPA's determination that Private Defendants' pesticide applications were substantially similar to its own was arbitrary and capricious.

discovery motions, this issue will be decided at this time. The remaining discovery issues will then be referred to the Magistrate Judge.

The Private Defendants contend that EPA's determination of the substantial similarity of their metolachlor products to Syngenta's is not reviewable by this Court because it is committed to the Agency's discretion by law.

There exists a strong presumption that agency actions are reviewable under the Administrative Procedure Act ("APA"). State of N.D. ex rel. Bd. of Univ. & Sch. Lands v. Yeutter, 914 F.2d 1031, 1033 (8th Cir. 1990). However, an exception to this presumption is present when: (1) statutes preclude judicial review, or (2) agency action is committed to agency discretion by law. 5 U.S.C. § 701(a); see also Yeutter, 914 F.2d at 1033. EPA argues that the agency action at issue here – EPA's determination of whether the me-too metolachlor applications were substantially similar under § 136a(c)(7)(A) – falls into this second exception.

Generally, "actions are committed to agency discretion where it is not possible to devise an adequate standard of review for an agency action." Ngure v. Ashcroft, 367 F.3d 975, 982 (8th Cir. 2004) (citing ICC v. Bhd. of Locomotive Eng'rs, 482 U.S. 270, 282, 107 S. Ct. 2360, 2367 (1987)). This situation arises where the relevant statute "is drawn so that a court would have no meaningful standard against which to judge an agency's exercise of discretion." Heckler v. Chaney, 470 U.S. 821, 830, 105 S. Ct 1649, 1655 (1985). Thus, courts often ask whether there is sufficient "law to apply" in order to review the agency's

action. Ngure, 367 F.3d at 982; see also Madison-Hughes v. Shalala, 80 F.3d 1121, 1127 (6th Cir. 1996) (“If regulations do not provide guidance about specific legal standards for judicial review, agency action is immune from such review.”).

Syngenta contends that the provisions of FIFRA, specifically § 3(c)(7)(A), provide guidance to the court on what law is to be applied to review EPA’s determination of substantial similarity. 7 U.S.C. § 136 *et. seq.*; 7 U.S.C. § 136a(c)(7)(A). However, FIFRA § 3(c)(7)(A) states:

The Administrator *may* conditionally register or amend the registration of a pesticide if the Administrator *determines* that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment . . .

7 U.S.C. 136a(c)(7)(A) (emphasis added). This language strongly suggests deference to the EPA Administrator’s determination of what pesticides are “substantially similar.” For example, in Webster v. Doe, 486 U.S. 592, 108 S. Ct. 2047 (1988), the Supreme Court held that statutory language allowing termination whenever the agency Director “shall deem such termination necessary or advisable . . . fairly exudes deference to the Director” and therefore the application of any meaningful standard of review by the court was foreclosed. Id. at 600. In State of North Dakota v. Yuetter, 914 F.2d at 1031, the Eighth Circuit, relying on Webster, concluded that a statute which read “if the Secretary *determines*” that certain conditions exist, provided no meaningful standard and therefore precluded judicial review. Id. at 1035 (emphasis added); see also Nickelson v. United States,

284 F. Supp. 2d 387, **390 n.3 (E.D. Va. 2003)** (relying on Webster and finding that language which provides “Secretary *may* authorize” grants deference to the Secretary and foreclos[es] the application of any meaningful judicial standard of review”) (emphasis in original); c.f. Mironescu v. Rice, 2006 WL 167981, at *7 (M.D.N.C. 2006) (distinguishing statute which reads “No state shall . . . extradite . . .” from the discretionary language found in Webster).

The regulations relied upon by Syngenta also fail to clarify how the EPA’s substantial similarity determination should be reviewed by this Court. Syngenta relies on 40 C.F.R. § 158.155 which lists the product composition information – i.e., the active ingredient, inert ingredients, and toxicological significant impurities – that must be furnished for each pesticide submitted to the EPA. See 40 C.F.R. § 158.155. Additionally, 40 C.F.R. § 158.150(b)(ii) explains that the product composition data is used to determine whether a product is identical or substantially similar to another product. 40 C.F.R. § 158.150(b)(iii). However, neither of these regulations provide any direction as to how that data should be considered when making this determination. Syngenta has not pointed to any regulations that provide guidelines, criteria or parameters regarding how EPA evaluates and compares the product composition information.

Syngenta also relies on an internal EPA guidance memorandum, written by Donald Stubbs, Acting Section Head Product Chemistry Review Section of the EPA on July 24, 1990, to establish factors to be considered in determining whether

products are identical or substantially similar. (Pl.'s Opp'n Br. 8-9.) The internal EPA memorandum provides guidelines for Product Chemists at the EPA to use when determining whether a product is substantially similar to a registered pesticide. (Private Defs' Mot. Protective Or., Ex. 3.) However, this internal EPA memorandum is more than 15 years old and there is no evidence it is still followed by the EPA. Additionally, although it specifies with some detail what factors may be important to a similarity determination, it also expressly notes: "Similarity determinations are a complex process, and involve a great deal of judgement on the part of the reviewer making the comparison. Any process that involves judgement will not achieve 100% accuracy or consistency, particularly from one reviewer to the next." (Id. at 2.) Thus, even this internal EPA memorandum intended to provide some guidance to the substantial similarity determination process suggests that this process is inherently discretionary.

In the aggregate these statutes, regulations, and internal memorandum simply fail to provide a meaningful standard against which a court can evaluate Syngenta's claim that EPA's finding that Private Defendants' applications were substantially similar was arbitrary and capricious. See Mass. Public Interest Res. Group, Inc. v. U.S. Nuclear Regulatory Com., 852 F.2d 9, 14-18 (1st Cir. 1988) (holding that where regulations, agency policy statements and internal standards failed to limit the agency's discretion, the decision was not subject to judicial review). Because the determination of the substantial similarity of the Private

Defendant's metolachlor applications to Syngenta's application is committed to the discretion of the EPA, it is not reviewable under § 701(a) of the APA. 5 U.S.C. § 701(a).⁵

This the day of March 31, 2006

/s/ N. Carlton Tilley, Jr.
United States District Judge

⁵ Generally the unreviewability of an agency action under the APA would not preclude judicial review of any accompanying constitutional claims. See Webster, 486 U.S. at 603. However, because none of Syngenta's constitutional claims relate to the EPA's determination of substantial similarity, this distinction is not relevant to this case.